

REMARKS

Claims 1-12 are pending. Claim 1 has been amended to correct a typographical error and to further define the molar ratios of 3-hydroxybutyrate and 3-hydroxyhexanoate in the copolymer. Support for the amendments can be found at least in page 5, lines 6-8 and page 16, Table 1 of the specification. Claim 5 has been amended to correct a typographical error. No new matter has been introduced. Upon entry of this amendment, claims 1-12 will be pending.

Specification

Applicants thank Examiner Sanders for the telephone interview on September 10, 2008. During the interview, Applicants explained that the specification of the present application as shown in the Patent Application Information Retrieval (PAIR) system and as published in US2006/0258833 is not the correct specification filed April 29, 2005, but instead the specification of WO 01/30892, a reference cited in the Information Disclosure Statement filed April 29, 2005.

A copy of the correct specification as originally filed on April 29, 2005 is submitted herewith, as requested by the Examiner. Applicants further note that the correct specification filed April 29, 2005 is in the PAIR system with a mail room date of April 29, 2005 and a document description of "Documents submitted with 371 Applications." Therefore, it appears that the specification of the application and that of the prior art WO 01/30892 were mistakenly switched during the Patent Office's processing. Applicants respectfully request the correction of this mistake.

Claim Rejections under 35 USC 112

Claims 1-9 are rejected under 35 USC 112, second paragraph, as alleged being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants respectfully traverse the rejections.

Specifically, the Office Action contends that it is not clear whether Applicants intend the present claims to recite a copolymer of 3-hydroxybutyrate and 3-hydroxyhexanoate or a copolymer comprising 3-hydroxybutylate and 3-hydroxyhexanoate. Applicants point out that claim 1 is supported at least by the first

paragraph of the specification. Applicants note that the “l” in “3-hydroxybutylate” was a typographical error, and have amended both the specification and claim 1 accordingly. Applicants further point out that it would have been obvious to one skilled in the art, in view of the specification, to understand that “3-hydroxybutylate” means 3-hydroxybutyrate, because the former is a misspelled word that does not have a meaning of its own.

For at least the reasons stated above, withdrawal of the rejections is respectfully requested.

Claim rejections under 35 USC 103 over WO 99/64498

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 99/64498 (“the ‘498 publication”). Applicants traverse the rejections.

The Office Action acknowledges that the ‘498 publication is silent as to molecular weight and flexural modulus, but contends that, because the polymers disclosed in the ‘498 publication are essentially the same as those recited in the claims, they are expected to possess properties or to be readily synthesized to possess these properties, in a manner to achieve the objective of the invention. Applicants respectfully disagree. The ‘498 publication merely discloses a list of polymers with various monomer units. There is no teaching whatsoever in the ‘498 publication as to what molecular weight and flexural modulus to pick for any polyhydroxyalkanoate polymers, let alone specifically for a copolymer (“PHBH”) comprising 3-hydroxybutyrate (“3HB”) and 3-hydroxyhexanoate (“3HH”), as recited in the claims.

On the other hand, Applicants have found that a flexural modulus of 100 to 1500 MPa in PHBH achieves unexpected superior results in terms of rigidity and crystallization rate. For example, as stated in page 5, line 25 to page 6, line 3, with a flexural modulus of less than 100MPa, the crystallization would be too slow in relation with the 3HH composition.

To clarify the relation between the flexural modulus and the molar ratios of 3HH and 3HB in PHBH, Applicants have amended claim 1 to recite “a copolymer comprising

97% to 75 % by mole of 3-hydroxybutyrate and 3% to 25 % by mole of 3-hydroxyhexanoate, which has a flexural modulus of 100 to 1500 MPa...” Applicants have found, surprisingly, that not only the flexural modulus of a copolymer varies with the monomer molar ratio, but the effect of the monomer molar ratio on the flexural modulus also depends on the what monomers are used. Applicants submit herewith a Declaration (“the Declaration”) under 37 CFR 1.132 by Kenichi Senda, a named inventor of the present application. The results in Experiment (1) of the Declaration include the flexural modulus and the monomer ratio of three Examples and three Comparative Examples in the specification as well as those of two more examples of PHBH and two more examples of copolymer (“PHBV”¹) of 3HB and 3-hydroxyvalyate (“3HV”). As shown in the figure on page 2 of the Declaration, the flexural modulus varies with the molar ratio of 3HH in PHBH as well as the molar ratio of 3HV in PHBV, but at a different rate. As such, the flexural modulus range of 100 to 1500 MPa, as recited in the claims, corresponds to a 3HH molar ratio range of 3% to 25 %, when 3HH and 3HB are used as monomers, but not when 3HV and 3HB are used as monomers.

The 3% to 25 % 3HH as recited in the claims are beneficial and could not have been obvious to one of ordinary skill in the art. Applicants point out that, as stated in page 5, lines 6-15, a 3HH molar ratio of 3% to 25 % is beneficial because less than 3% of 3HH leads to flexibility lost and too high a processing temperature for forming film. Also, more than 25% of 3HH results in too slow a crystallization rate. The range could not have been obvious, at least because (a) the monomer ratio had not been recognized as a result-effective variable for altering flexural modulus, and (b) the relation between the monomer ratio and the flexural modulus is monomer-specific. For example, as shown in Table 1 of the specification and in the figure on page 2 of the Declaration, with a 3HV molar ratio of 3% to 25 %, the flexural modulus of the copolymer PHBV cannot be 100 to 1500 MPa, as recited in the claims.

¹ The Office Action contends that PHBV is equated by the ‘498 publication to PHBH on page 7. However, page 7, lines 4-5 of the ‘498 publication indicates that PHBV refers to poly-3-hydroxybutyrate-co-3-hydroxyvalerate. Applicants further point out that a valerate has 5 carbons while a butyrate has 4 carbons. Therefore, PHBV and PHBH are different copolymers.

For at least the reasons stated above, a *prima facie* case of obviousness has not been established. Withdrawal of the rejections is respectfully requested.

Claim rejections under 35 USC 103 over WO 99/64498 and EP0809669

Claims 5 and 10-12 are rejected under 35 USC 103(a) as allegedly being unpatentable over the '498 publication and further in view of EP 0809669 ("the '669 publication"). Applicants traverse the rejections.

As stated above, the '498 publication does not teach or suggest, *inter alia*, the 3HH monomer molar ratio or the flexural modulus as recited in the claims. The deficiency is not cured by the '669 publication, because it does not teach or suggest the 3HH monomer molar ratio or the flexural modulus as recited in the claims either. Applicants point out that the molar ratio ranges disclosed in paragraph [0012] of the '669 publication specifically refers to PHBV only².

Moreover, none of the '498 publication and the '669 publication, alone or in combination, teaches or suggests the processes of applying mechanical shearing to an aqueous dispersion, as recited in claims 5 and 10. The '498 publication does not teach or suggest a mechanical shearing process at all. The '669 publication discloses a process of making PHA latex comprising making a liquid-form solution of such PHA in a water-soluble liquid and contacting that solution with water under shearing. The water-soluble liquid include **organic solvent** only. See paragraph [0021]. Therefore, the shearing process of the '669 publication is not applied to an **aqueous solution**, as required by claims 5 and 10. As such, the cited references do not teach or suggest all of the limitations of claims 5 and 10.

Additionally, Applicants point out that the use of a mixture of an organic solvent and water such as those disclosed in the '669 publication would lead to a reduction of molecular weight of PHBH. In Experiment (2) of the Declaration, PHBH of a molecular weight of 1,500K was dispersed in liquid with various water/ethanol contents and subjected to mechanical shearing. As the results clearly show and as stated on page 3 of the Declaration, the molecular weight of the PHBH was reduced when the dispersion

² In a repeating unit -O-CmHn-CO-, m=4 corresponds to valerate and m=3 correspond to butyrate.

liquid contained ethanol, while remained the same when the dispersion was aqueous.

For at least the reasons stated above, a *prima facie* case of obviousness has not been established. Withdrawal of the rejections is respectfully requested.

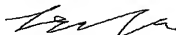
CONCLUSION

Applicants submit that the claims are allowable and an early and favorable action to that effect is respectfully requested.

The Examiner is invited to contact the undersigned to discuss any issues regarding this application.

In the event that the filing of this paper is deemed not timely, applicants petition for an appropriate extension of time. The Office is authorized to charge any underpayment or credit any overpayment to Kenyon & Kenyon LLP's Deposit Account No. 11-0600.

Respectfully submitted,
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Enclosures:

1. Specification as filed on April 29, 2005
2. Declaration under 37 CFR 1.132